§ 225.158 Laboratory assays.

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

§ 225.165 Equipment cleanout procedures.

Adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

Subpart H—Labeling

§ 225.180 Labeling.

Labels shall be received, handled, and stored in a manner that prevents label mixups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used.

[51 FR 7390, Mar. 3, 1986]

Subpart I—Records

§ 225.202 Formula, production, and distribution records.

Records shall be maintained identifying the formulation, date of mixing, and if not for own use, date of shipment. The records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Such records shall be retained on the premises for 1 year following the date of last distribution.

(Approved by the Office of Management and Budget under control number 0910–0152)

[51 FR 7390, Mar. 3, 1986]

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

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226.102 Master-formula and batch-production records.
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AUTHORITY: 21 U.S.C. 351, 352, 360b, 371, 374.

SOURCE: 40 FR 14031, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 226.1 Current good manufacturing practice.

(a) The criteria in §§ 226.10 through 226.115, inclusive, shall apply in determining whether the methods used in, or the facilities and controls used for the manufacture, processing, packing, or holding of a Type A medicated article(s) conform to or are operated or administered in conformity with current good manufacturing practice to assure that a Type A medicated article(s) meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this part 226 permit the use of precision, automatic, mechanical, or electronic equipment in the production of a Type A medicated article(s) when adequate inspection

and checking procedures or other quality control procedures are used to assure proper performance.

(b) In addition to maintaining records and reports required in this part, Type A medicated articles requiring approved NADAs are subject to the requirements of § 514.80 of this chapter.

[40 FR 14031, Mar. 27, 1975, as amended at 68 FR 15364, Mar. 31, 2003]

§ 226.10 Personnel.

The key personnel and any consultants involved in the manufacture and control of the Type A medicated article(s) shall have a background of appropriate education or appropriate experience or combination thereof for assuming responsibility to assure that the Type A medicated article(s) has the proper labeling and the safety, identity, strength, quality, and purity that it purports to possess.

Subpart B—Construction and Maintenance of Facilities and Equipment

§ 226.20 Buildings.

Buildings in which Type A medicated article(s) are manufactured, processed, packaged, labeled, or held shall be maintained in a clear and orderly manner and shall be of suitable size, construction and location in relation to surroundings to facilitate maintenance and operation for their intended purpose. The building shall:

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which they are employed to minimize risk of mixups between different Type A medicated article(s), their components, packaging, or labeling:

(1) The receipt, sampling, control, and storage of components.

(2) Manufacturing and processing operations performed on the Type A medicated article(s).

(3) Packaging and labeling operations.

(4) Storage of containers, packaging materials, labeling, and finished products.

(5) Control laboratory operations.

(b) Provide adequate lighting and ventilation, and when necessary for the intended production or control purposes, adequate screening, dust and temperature controls, to avoid contamination of Type A medicated article(s), and to avoid other conditions unfavorable to the safety, identity, strength, quality, and purity of the raw materials and Type A medicated article(s) before, during, and after production.

(c) Provide for adequate washing, cleaning, toilet, and locker facilities.

Work areas and equipment used for the production of Type A medicated article(s) or for the storage of the components of Type A medicated article(s) shall not be used for the production, mixing or storage of finished or unfinished insecticides, fungicides, rodenticides, or other pesticides or their components unless such materials are recognized as approved drugs intended for use in animal feeds.

§ 226.30 Equipment.

Equipment used for the manufacture, processing, packaging, bulk shipment, labeling, holding, or control of Type A medicated article(s) or their components shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate maintenance and operation for its intended purpose. The equipment shall:

(a) Be so constructed that any surfaces that come into contact with Type A medicated article(s) are suitable, in that they are not reactive, additive, or absorptive to an extent that significantly affects the identity, strength, quality, or purity of the Type A medicated article(s) or its components.

(b) Be so constructed that any substance required for the operation of the equipment, such as lubricants, coolants, etc., may be employed without hazard of becoming an unsafe additive to the Type A medicated article(s).

(c) Be constructed to facilitate adjustment, cleaning, and maintenance, and to assure uniformity of production and reliability of control procedures and to assure the exclusion from Type A medicated article(s) of contamination, including cross-contamination from manufacturing operations.